

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.:	tba	Art Unit:	1615
Filed:	tba	Examiner:	S. Tran
1 st Inventor:	SHIMIZU, T.	Allowed:	
For:	Orally Disintegrable Tablets	Batch:	
Atty. Dkt. No.	2522 US2P	Paper No.:	

PRELIMINARY AMENDMENT

Box NEW APPLICATION

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

AMENDMENT

In the Specification

Please insert on Page 1 as the first sentence of the application the following:

-- This application is a continuation of U.S. Patent Application Serial No. 09/355,781, now U.S. Patent No. _____, issued _____, which was the National Phase filing of International Patent Application No. PCT/JP99/02548, filed May 17, 1999. --

In the Claims

Please substitute the following Claim 1 as Amended for Claim 1.

Please substitute the following Claim 32 as Amended for Claim 32.

Please cancel Claims 10 and 37 without prejudice to filing future continuing applications.

1. (AMENDED) An orally disintegrable tablet which comprises

(i) fine granules having an average particle diameter of 400 μm or less, which fine granules comprise a composition coated by an enteric coating layer comprising a first component which is an enteric coating agent and a second component which is a sustained release agent, said composition having 10 weight % or more of an acid-labile physiologically active substance and

(ii) an additive wherein said tablet having a hardness strength of about 1 to about 20 kg is orally disintegrable.

32. (AMENDED) Fine granules having an average particle diameter of 400 μm or less, which comprise a composition coated by an enteric coating layer comprising a first component which is an enteric coating agent and a second component which is a sustained release agent, said composition having (i) 25 weight % or more of an acid-labile physiologically active substance and (ii) a basic inorganic salt.

Mark-up of Amendment to Claims

1. (AMENDED) An orally disintegrable tablet which comprises
 - (i) fine granules having an average particle diameter of 400 μm or less, which fine granules comprise a composition coated by an enteric coating layer comprising a first component which is an enteric coating agent and a second component which is a sustained release agent, said composition having 10 weight % or more of an acid-labile physiologically active substance and
 - (ii) an additive wherein said tablet having a hardness strength of about 1 to about 20 kg is orally disintegrable.

10. (Canceled)

32. (AMENDED) Fine granules having an average particle diameter of 400 μm or less, which comprise a composition coated by an enteric coating layer comprising a first component which is an enteric coating agent and a second component which is a sustained release agent, said composition having (i) 25 weight % or more of an acid-labile physiologically active substance and (ii) a basic inorganic salt.

37. (Canceled)

REMARKS

I. Amendments

Reference to Prior applications is inserted into the specification by this amendment.

Claim 1 has been amended to recite that the tablet has a hardness strength of about 1 kg to about 20 kg and is orally disintegrable. Support for this amendment is found in the specification and claims as filed (for example, on page 23, lines 9-11).

Claims 1 and 32 have been amended to further clarify the composition of the claimed invention as having an enteric coating layer "comprising a first component which is an enteric coating agent and a second component which is a sustained release agent."

Claims 10 and 37 have been canceled without prejudice.

II. Conclusion

Early allowance of the claims is requested. Should the Examiner believe that a conference with applicants' attorney would advance prosecution of this application, she is respectfully requested to call applicants' attorney at (847) 383-3372.

Respectfully submitted,



Dated: October ³⁰~~25~~, 2001

(847)383-3372
(847)383-3391

Mark Chao, Ph.D., Reg. No. 37,293
Elaine M. Ramesh, Ph.D., Reg. No. 43032
Attorney for Applicants
Customer No. 23115

Takeda Pharmaceuticals North America, Inc.
Intellectual Property Department
Suite 500, 475 Half Day Road
Lincolnshire, IL 60069 USA